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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/902,692	07/30/1997	WILLIAM J. REA	16715CIP	1465

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TODD E ALBANESI
CRUTSINGER & BOOTH
1601 ELM STREET SUITE 1950
THANKSGIVING TOWER
DALLAS, TX 752014744

EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/902,692	REA ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/30/06 entered.

2. Claims 49-64 are under consideration.

3. The rejection of claims 49-64 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons elaborated in the previous Office Action are withdrawn in view of the amended claims.

4. The rejection of claims 49-64 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons elaborated in the previous Office Action are withdrawn in view of the amended claims.

5. Regarding priority for the claimed invention and the application of prior art, the scope of the claimed invention is not disclosed in parent application 08/380063 and therefore the instant application is not entitled to priority to said application regarding the application of prior art. The claims of the instant application encompass treatment of chemically sensitive patients per se regardless of etiology of the disease. The parent application is generally drawn to methods of treatments wherein the patient requires regulation of the cell cycle (for example see original claims). The parent application does not disclose treatment of chemically sensitive patients per se, regardless of the etiology of said disease. Regarding the clinical testing on pages 9-10 of 08/380063, said example discloses the patients were chemically sensitive, chronically ill patients with a particular subset of symptoms (see page 9) and that the patients all showed irregular cell cycles (see page 10). The claims of the instant application encompass treatment of chemically sensitive patients that do not have an abnormal cell cycle or are not represented by the particular types of patient referred to in page 9. Furthermore, the method disclosed in pages 9-10 includes a step wherein the cell cycle of the patient is

analyzed by DNA histogram prior to treatment and such a step is not included in the claims of the instant application.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 49 is rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention as evidenced by Griffiths.

Griffiths discloses use of the method of claim 49 to treat environmentally ill patients wherein "chemically sensitive individual" would be encompassed by the term "environmentally ill patients" (see entire reference). Lymphocytes were harvested form a blood sample of patient wherein lymphocytes would contain T and B lymphocytes (see page 7). The lymphocytes were cultured and stimulated to blast (aka propagated), lysed and the lysate was administered to the patient (see page 7).

8. An issue of public use or on sale activity has been raised in this application. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows. Additional information is required as to whether the claimed invention was disclosed at other meetings or symposiums or used commercially prior to the filing date of the instant application or parent applications.

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 49-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths in view of Youdim et al., Warren (US Patent 4,435,384), Goust et al. (US Patent 4,001,080) and Lane et al.

Griffiths discloses use of the method of claim 49 to treat environmentally ill patients wherein "chemically sensitive individual" would be encompassed by the term "environmentally ill patients" (see entire reference). Lymphocytes were harvested from blood samples of patients wherein lymphocytes would contain T and B lymphocytes (see page 7). The lymphocytes were cultured and stimulated to blast (aka propagated), lysed and the lysate was administered to the pateint (see page 7). Griffiths does not teach the particular steps recited in the claims 50-64. Griffiths teaches that the autologous factor can be produced by culturing/propagating PBL in vitro followed by lysis of said cells to produce a lysate containing autologous factor. The PBL are contained in a blood sample. Warren teaches the use of heparinized tubes to collect the blood sample. The use of commercially available density gradients such as HYPAQUE-FICOLL (a well known commercially available version of the agent recited in claim 51/claim 60 part(b)) using the steps recited in the claims to isolate/separate lymphocytes is well known in the art (for example see Lane et al., page 66.2). The culture of lymphocytes at 37 degrees C (aka 98.6 Fahrenheit aka body temperature) is standard operating procedure (for example Warren teaches 37 degree incubation of lymphocytes (see column 2)). Goust et al. teach use of bovine calf serum in the culture process to produce

lymphocyte factors from cultured lymphocytes (see Example 3, column 5 wherein fetal calf serum is encompassed by the term bovine calf serum). Goust et al. teach that new media is added as needed (see Example 3, column 5). While Goust et al. teach that the lysate is obtained via freezing and thawing cells, Goust et al. teach that the lymphocyte factor can be produced by disrupting the cells wherein sonication is an art known procedure for disrupting cells. Warren teaches that lymphocyte factor can be produced by a variety of different methods. Centrifugation and washing of cultured cells are routine tissue culture steps for cells grown in suspension. Griffith teaches parental administration of the factor wherein subcutaneous administration is an art known form of parental administration. Youdim et al. teaches multiple administration of lymphocyte factor (see page 56, column 2). Youdim et al. teaches that skin testing (eg. DTH) can be used to measure the response to lymphocyte factor. A routineer would have evaluated the patient pre and post treatment to determine the efficacy of treatment and to determine if further treatment was required. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Griffiths discloses use of the method of claim 49 to treat environmentally ill patients wherein "chemically sensitive individual" would be encompassed by the term "environmentally ill patients" and the other steps recited in the claims other than 49 represent art known culture steps or modes of administration. One of ordinary skill in the art would have been motivated to do the aformentioned because Griffiths teaches the method of claim 49 and the other claims represent art known procedures that would be used to execute the method of claim 49.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1950~~ 1644

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644